UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

June 13, 2011

MEMORANDUM

Subject: Efficacy Review for SDC3A; EPA Reg. No. 72977-5; DP Barcode: D387657.

From: Ibrahim Laniyan, Ph.D.
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To: Marshall Swindell / Martha Terry
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: ETI H2O, Inc.
1725 Gillespie Way
El Cajon, CA 92020

Formulation from the Label:

Active Ingredient	% by wt.
Citric Acid	4.846 %
Silver	0.003 %
Other ingredients	95.151 %
Total	100.000 %

I. BACKGROUND

The product, SDC3A (EPA Reg. No. 72977-5), is an EPA-approved disinfectant (bactericide, fungicide, virucide), sanitizer, and deodorizer for use on pre-cleaned, hard, non-porous surfaces in household, commercial, institutional, food preparation, animal care, and hospital or medical environments. The applicant requested to amend the registration of this product to add new claims for effectiveness as a disinfectant against Carbapenem-Resistant *Escherichia coli*, Carbapenem-Resistant *Klebsiella pneumoniae*, *Klebsiella pneumoniae bla* NDM-1, Hepatitis B virus, and Hepatitis C virus. The applicant is also requesting to update the "kill time" for *Trichophyton mentagrophytes* and numerous viruses. Studies were conducted at BioScience Laboratories, Inc., located at 300 N. Willson Avenue, in Bozeman, MT 59715; and ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated March 1, 2011), nineteen studies (MRID 484070-01 through 484070-19), Statements of No Data Confidentiality Claims for all nineteen studies, and the proposed label.

Note: A number of the laboratory reports describe studies conducted for the product, Axen30. The letter to EPA (dated March 1, 2011) states that the tested product, Axen30, is identical in composition to the product, SDC3A, which is the subject of this efficacy report. A number of the laboratory reports describe studies conducted for the product, SDC.0003.AA0. The letter to EPA (dated March 1, 2011) states that the name, SDC.0003.AA0, is an internal identifier for the product, SDC3A, which is the subject of this efficacy report.

II. USE DIRECTIONS

The product is designed for disinfecting and sanitizing hard, non-porous surfaces. The product may be used to treat hard, non-porous surfaces, including: activity centers, air conditioning vents, animal feeding dishes, appliances, baby furniture, bakery equipment, bathtubs, bed frames, beverage bar equipment, blenders, booster chairs, bottling equipment, breast pump parts, buffet counters, cabinets, cages, canning equipment, chairs, child car seats, chopping blocks, computer keyboards, concession equipment, conveyor systems, cooking equipment, coolers, counters, cutting boards, desks, diaper changing tables, diaper pails, dish racks, doorknobs, drain boards, drinking fountains, examination tables, faucet handles, filling line equipment, floors, food processing equipment, grocery carts, handrails, jungle gyms, lab benches, labeling machines, laundry hampers, light switch covers, litter boxes, lunch boxes, mixing equipment, packaging equipment, patio furniture, picnic tables, playhouses, potty seats, processing vessels, refrigerated display equipment, remote controls, salad bars, showers, sinks, storage tanks, strollers, tables, tanning beds, telephones, toilets, toy boxes, toys, urinals, walls, waste containers, and wheelchairs. The proposed label indicates that the product may be used on hard, non-porous surfaces, including: acrylic, butyl rubber (EPDM), fiberglass, Formica, glass, glazed porcelain, glazed tile, linoleum, metal, naugahyde, neoprene, non-porous vinyl, painted surfaces, plastic, plasticized PVC, polyurethane, sealed granite, sealed marble, silicone, Teflon, and Viton. Directions on the proposed label provide the following information regarding use of the product as a disinfectant: Pre-clean surfaces prior to using the product. Apply, spray, or mist surfaces until thoroughly wet for 2 minutes (for 1 minute against viruses; for 5 minutes against fungi) or for the specific contact time specified on the product label. The surface may then be wiped dry with a clean towel.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): *Effectiveness of disinfectants against specific bacteria other than those named in the* AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Disinfectants for Use in Hospital or Medical Environments; Batch Replication for Modified Test; Different Exposure Period: Under certain circumstances, an applicant is permitted to rely on previously submitted efficacy data to support supplemental efficacy claims for fungicides, tuberculocides, and virucides under modified conditions (e.g., different exposure period). Additional testing may be conducted with reduced batch replications. Specifically, data may be developed on the applicant=s own finished product, at the same use concentration, for one product sample, instead of two product samples.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Use-Dilution Method): The effectiveness of liquid disinfectants against specific pathogenic *fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution* Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for *each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of* at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Virucides – Novel Virus Protocol Standards: To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 484070-01 "A Hard Surface Disinfection Evaluation of One Test Formulation Versus Two Bacterial Species," Test Organisms: *Escherichia coli* (BSLI #082710-EcCP1) and *Klebsiella pneumoniae* (BSLI #081710KPC4), for SDC3A, by Terri Eastman. Study conducted at BioScience Laboratories, Inc. Study completion date – February 10, 2011. Laboratory Study Number 100918-204.

This study was conducted against Carbapenem-Resistant *Escherichia coli* (Clinical isolate; BSLI #082710-EcCP1) and Carbapenem-Resistant *Klebsiella pneumoniae* (Clinical isolate; BSLI #081710KPC4). Two lots (Lot Nos. P09299002 and P10231001) of the product, SDC3A, were tested using the BioScience Laboratories, Inc. protocol # 100918-204 (copy provided). The product was received ready-to-use. Cultures of the challenge microorganisms were prepared in accordance with the published AOAC methods, with the following exception: the cultures were incubated for 48-54 hours at 35±2°C. For testing conducted on October 26, 2010, heat-inactivated fetal bovine serum was added to each culture to achieve a 5% organic soil load. For testing conducted on December 23, 2010, the product was not tested in the presence of a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot per microorganism were immersed for 15±2 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried in an incubator for 40±2 minutes at 35±2°C. Each carrier was placed in 10 mL of the product for 2 minutes at 25±1°C. The tubes containing the product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to 20 mL of Fluid Thioglycollate Medium to neutralize. All subcultures were incubated for 48±2 hours at 35±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, growth, neutralization confirmation, and antibiotic resistance.

Note: Testing conducted on October 26, 2010 against both microorganisms showed growth in subcultures of 1 of the 10 carriers for Lot No. P10231001. Testing was repeated on December 23, 2010 with no organic soil load.

Note: Antibiotic resistance of Carbapenem-Resistant *Escherichia coli* (Clinical isolate; BSLI #082710-EcCP1) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. The measured zone of inhibition confirmed antibiotic resistance of Carbapenem-Resistant *Escherichia coli* (Clinical isolate; BSLI #082710-EcCP1) to imipenem. See pages 14 and 15 of the laboratory report.

Note: Antibiotic resistance of Carbapenem-Resistant *Klebsiella pneumoniae* (Clinical isolate; BSLI #081710KPC4) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. The measured zone of inhibition confirmed antibiotic resistance of Carbapenem-Resistant *Klebsiella pneumoniae* (Clinical isolate; BSLI #081710KPC4) to imipenem. See pages 14 and 15 of the laboratory report.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

2. MRID 484070-02 "A Hard Surface Disinfection Evaluation of One Test Formulation Versus One Bacterial Species," Test Organism: *Klebsiella pneumoniae* bla_{NDM-1} (ATCC BAA-2146), for SDC3A, by Terri Eastman. Study conducted at BioScience Laboratories, Inc. Study completion date – February 14, 2011. Laboratory Study Number 110117-204.

This study was conducted against *Klebsiella pneumoniae* bla_{NDM-1} (ATCC BAA-2146). Two lots (Lot Nos. P09300001 and P10145001) of the product, SDC3A, were tested using the the BioScience Laboratories, Inc. protocol # 110117-204 (copy provided). The product was received ready-to-use. A culture of the challenge microorganism was prepared in accordance with the published AOAC methods, with the following exception: the culture was incubated for 48-54 hours at 35±2°C.The product was not tested in the presence of a 5% organic soil load. Ten (10) stainless steel penicylinder carriers per product lot were immersed for 15±2 minutes in a 48-54 hour old suspension of test organism, at a ratio of 1 carrier per 1 mL broth. The carriers were dried in an incubator for 40±2 minutes at 35±2°C. Each carrier was placed in 10 mL of the product for 2 minutes at 25±1°C. The tubes containing the product were swirled after addition of the carriers. Following exposure, individual carriers were transferred to 20 mL of Fluid Thioglycollate Medium to neutralize. All subcultures were incubated for 48±2 hours at 35±2°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, growth, neutralization confirmation, and antibiotic resistance.

Note: Antibiotic resistance of *Klebsiella pneumoniae* bla_{NDM-1} (ATCC BAA-2146) was verified on a representative culture. The laboratory performed a Kirby Bauer Susceptibility assay. The measured zone of inhibition (i.e., ≤19 mm) confirmed antibiotic resistance of *Klebsiella pneumoniae* bla_{NDM-1} (ATCC BAA-2146) to imipenem. See pages 14 and 15 of the laboratory report.

3. MRID 484070-03 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus," for SDC.0003.AA0, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – December 20, 2010. Project Number A10529.

This study, under the direction of Study Director Kelleen Gutzmann, was conducted against Duck hepatitis B virus (Strain 7/31/07; obtained from HepadnaVirus Testing Inc., Palo Alto, CA), using primary duck hepatocytes (cultures prepared by Valley Research Institute personnel using hatchling ducks received from Metzer Farms) as the host system. Two lots (Lot Nos. P09209001 and P10231001) of the product, SDC.0003.AA0, were tested according to ATS Labs Protocol No. IMS01101110.DHBV.1 (copy provided). The product was received ready-to-use. The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 40% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 21.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Primary duck

hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of the dilutions. The inoculum was allowed to absorb overnight at 36-38°C in a humidified atmosphere of 5-7% CO_2. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for a total of 9 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were re-fed, as necessary. On the final day of incubation, the cultures were scored microscopically for cytotoxicity. An indirect immunofluorescence assay was then performed. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

4. MRID 484070-04 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus as a Surrogate Virus for Human Hepatitis B Virus – Confirmatory Assay," for SDC.0003.AA0, by Shanen Conway. Study conducted at ATS Labs. Study completion date – November 29, 2010. Project Number A10419.

This confirmatory study, under the direction of Study Director Shanen Conway, was conducted against Duck hepatitis B virus (Strain 07/31/07; obtained from HepadnaVirus Testing Inc., Palo Alto, CA), using primary duck hepatocytes (cultures prepared by Valley Research Institute personnel using hatchling ducks received from Metzer Farms) as the host system. One lot (Lot No. P09209001) of the product, SDC.0003.AA0, was tested according to ATS Labs Protocol No. IMS01101110.DHBV.2 (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture contained 100% duck serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 30 minutes at 20.0°C at 40% relative humidity. Two replicates were tested. For the single lot of product, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Leibovitz L-15 medium with 0.1% glucose, 10 µM dexamethasone, 10 µg/mL insulin, 20 mM HEPES, 10 µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes in multi-well culture dishes were inoculated in quadruplicate with 1.0 mL of the dilutions. The inoculum was allowed to absorb overnight at 36-38°C in a humidified atmosphere of 5-7% CO_2. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation for a total of 9 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were re-fed, as necessary. On the final day of incubation, the cultures were scored microscopically for cytotoxicity. An indirect immunofluorescence assay was then performed. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

5. MRID 484070-05 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus," for SDC.0003.AA0, by Shanen Conway. Study conducted at ATS Labs. Study completion date – November 29, 2010. Project Number A10422.

This study, under the direction of Study Director Shanen Conway, was conducted against Bovine viral diarrhea virus (Strain Oregon C24v-genotype 1; obtained from the National Veterinary Services Laboratories, Ames, IA), using BT cells (bovine turbinate cells; ATCC CRL-1390; propagated in-house) as the host system. Two lots (Lot Nos. P09209001 and P10231001) of the product, SDC.0003.AA0, were tested according to ATS Labs Protocol No.

IMS01081910.BVD.2 (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% horse serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates per product lot were tested. For each lot of product, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns. A 0.2 mL aliquot of the test virus was re-suspended in 2.0 mL of the product. The filtrates then were diluted serially in Minimum Essential Medium with 5% (v/v) non-heat inactivated horse serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BT cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects (rounded, dark, with a granular appearance), cytotoxicity, and viability. On the final day of incubation, infectious virus was assayed by a direct immunofluorescence assay to verify the CPE reading. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

6. MRID 484070-06 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Bovine Viral Diarrhea Virus as a Surrogate Virus for Human Hepatitis C Virus – Confirmatory Assay," for SDC.0003.AA0, by Mary Miller. Study conducted at ATS Labs. Study completion date – October 15, 2010. Project Number A10236.

This confirmatory study, under the direction of Study Director Mary Miller, was conducted against Bovine viral diarrhea virus (Strain Oregon C24v-genotype 1; obtained from the National Veterinary Services Laboratories, Ames, IA), using BT cells (bovine turbinate cells; ATCC CRL-1390; propagated in-house) as the host system. One lot (Lot No. P09209001) of the product, SDC.0003.AA0, was tested according to ATS Labs Protocol No. IMS01081910.BVD.1 (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% horse serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates were tested. For the single lot of product, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns. A 0.2 mL aliquot of the test virus was re-suspended in ~2.0 mL of the product. The filtrates then were diluted serially in Minimum Essential Medium with 5% (v/v) non-heat inactivated horse serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. BT cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects (rounded, dark, with a granular appearance), cytotoxicity, and viability. On the final day of incubation, infectious virus was assayed by a direct immunofluorescence assay to verify the CPE reading. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

7. MRID 484070-07 "Fungicidal Use-Dilution Method, Test Organism: *Trichophyton mentagrophytes* (ATCC 9533)" for Axen30, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – March 9, 2010. Project Number A08935.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). One lot (Lot No. P09209001) of the product, Axen30, was tested using the ATS Laboratory Protocol No. IMS01112309.FUD (copy provided). The product was received ready to use. The product was not tested in the presence of an organic soil load. For each contact time, ten (10) stainless steel penicylinder carriers were immersed for 15 minutes in a 14-day old suspension of test organism, at a ratio of 1 carrier per 1 mL suspension. The carriers were dried for 40 minutes at 35-37°C at 47% relative humidity. Each carrier was placed in 10.0 mL of the product for 5 minutes or 6 minutes at 20.0°C. Following exposure, individual carriers were transferred to 10 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. Carriers were transferred from primary subculture tubes into individual secondary subculture tubes containing 10 mL of Sabouraud Dextrose Broth with 0.07% Lecithin and 0.5% Tween 80 at least 30 minutes following the first transfer. All subcultures were incubated for 10 days at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

8. MRID 484070-08 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rotavirus" for Axen30, by Shanen Conway. Study conducted at ATS Labs. Study completion date – May 26, 2010. Project Number A09460.

This study was conducted against Rotavirus (Strain WA; obtained from the University of Ottawa, Ontario, Canada), using MA-104 cells (Rhesus monkey kidney cells; obtained from Diagnostic Hybrids, Inc., Athens, OH; propagated in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01031810.ROT (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 30 seconds or 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in serum-free Minimum Essential Medium with 0.5 µg/mL trypsin, 2.0 mM L-glutamine, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. MA-104 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The inoculum was allowed to adsorb for 65 minutes at 36-38°C in a humidified atmosphere of 5-7% CO_2. Post-adsorption, the cultures were re-fed. The cultures were returned to incubation at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

9. MRID 484070-09 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Human Coronavirus" for Axen30, by Shanen

Conway. Study conducted at ATS Labs. Study completion date – May 26, 2010. Project Number A09445.

This study was conducted against Human coronavirus (Strain 229E; ATCC VR-740), using WI-38 cells (human embryonic lung fibroblasts; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01031810.COR (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 30 seconds or 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 2% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. WI-38 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 11 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

10. MRID 484070-10 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A (H1N1) virus" for Axen30, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – August 10, 2010. Project Number A09821.

This study was conducted against Influenza A (H1N1) virus (Strain A/PR/8/34; ATCC VR-1469), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01061710.FLUA (copy provided). he product was received ready-to-use, as a trigger spray. The stock virus culture contained 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 40% relative humidity. For the single lot of product, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

11. MRID 484070-11 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Swine Influenza A (H1N1) virus" for Axen30, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – August 12, 2010. Project Number A09820.

This study was conducted against Swine influenza A (H1N1) virus (Strain A/Swine/Iowa/15/30; ATCC VR-333), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01061710.SFLU (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture contained 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 40% relative humidity. For the single lot of product, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 30 seconds at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

12. MRID 484070-12 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Respiratory syncytial virus (RSV)" for Axen30, by Shanen Conway. Study conducted at ATS Labs. Study completion date – June 9, 2010. Project Number A09491.

This study was conducted against Respiratory syncytial virus (Strain Long; ATCC VR-26), using Hep-2 cells (human larynx carcinoma cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01042710.RSV (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 30 seconds or 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Eagle's Minimum Essential Medium with 2% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL Fungizone, 10 µg/mL vancomycin, 2 mM L-glutamine, and 10 mM HEPES. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls

included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

13. MRID 484070-13 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Adenovirus type 2" for Axen30, by Shanen Conway. Study conducted at ATS Labs. Study completion date – June 3, 2010. Project Number A09484.

This study was conducted against Adenovirus type 2 (Strain Adenoid 6; ATCC VR-846), using A-549 cells (human lung carcinoma cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01042710.ADV (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 30 seconds or 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Eagle's Minimum Essential Medium with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL Fungizone, and 10 mM HEPES. A-549 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

14. MRID 484070-14 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Avian Influenza A (H3N2) virus (Avian Reassortant)" for Axen30, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 25, 2010. Project Number A09124.

This study was conducted against Avian influenza A (H3N2) virus (Avian Reassortant (Strain A/Washington/897/80 X A/Mallard/New York/6750/78; ATCC VR-2072), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01112309.AFLU (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 30 seconds or 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were

inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 8 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

15. MRID 484070-15 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus" for Axen30, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 29, 2010. Project Number A09125.

This study was conducted against Influenza A virus (Strain Hong Kong; ATCC VR-544), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01112309.FLUA (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture contained 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 40% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 30 seconds or 1 minute at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents.The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 8 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

16. MRID 484070-16 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Murine Norovirus (MNV-1)" for Axen30, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – April 9, 2010. Project Number A09245.

This study was conducted against Murine norovirus (MNV-1) (Strain MNV-1.CW1; obtained from Washington University, St. Louis, MO), using RAW 264.7 cells (a continuous mouse macrophage cell line; obtained from Washington University, St. Louis, MO; propagated in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01112309.MNV (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute or 3 minutes at 20°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Complete 2X MEM. RAW 264.7 cells in

multi-well culture dishes were inoculated in quadruplicate with 250 µL of the dilutions. The inoculum was allowed to adsorb for ~60 minutes at room temperature. Post-adsorption, the media was aspirated and an aliquot of MNV Overlay Agarose I was added to each well. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2 for ~2 days. Following incubation, an aliquot of MNV Overlay Agarose II containing neutral red stain was added, and the cultures were returned to incubation for ~2 hours. The cultures were scored for the presence or absence of viral specific plaques and cytotoxicity. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

17. MRID 484070-17 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus – Confirmatory Assay" for Axen30, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – April 19, 2010. Project Number A09247.

This confirmatory study, under the direction of Study Director Kelleen Gutzmann, was conducted against Feline calicivirus (Strain F-9; ATCC VR-782), using CRFK cells (Crandel Reese feline kidney cells; ATCC CCL-94; propagated in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01112309.FCAL (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. Two replicates were tested. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute or three minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns. A 0.2 mL aliquot of the test virus was re-suspended in ~2.0 mL of the product. The filtrates then were diluted serially in Minimum Essential Medium with 5% (v/v) heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of cytopathic effects (small, rounding of the cells, with a slight granular look), cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

18. MRID 484070-18 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rhinovirus type 37" for Axen30, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – March 29, 2010. Project Number A09043.

This study was conducted against Rhinovirus type 37 (Strain 151-1; ATCC VR-1147), using MRC-5 cells (human embryonic lung cells; ATCC CCL-171; propagated in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01112309.R37 (copy provided). The product was received ready-to-use.

The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 50% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute, 3 minutes, or 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 10% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

19. MRID 484070-19 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Poliovirus type 2" for Axen30, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 24, 2010. Project Number A09123.

This study was conducted against Poliovirus type 2 (Strain Lansing; ATCC VR-1002), using Vero cells (ATCC CCL-81; propagated in-house) as the host system. One lot (Lot No. P09209001) of the product, Axen30, was tested according to ATS Labs Protocol No. IMS01112309.POL (copy provided). The product was received ready-to-use, as a trigger spray. The stock virus culture contained 1% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 15.5°C at 55% relative humidity. For each contact time, separate dried virus films were sprayed (3 sprays) with the product at a distance of 6-8 inches from the carrier surface until thoroughly wet. The carriers were allowed to remain wet for 1 minute, 3 minutes, or 5 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 5% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. Vero cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

V. RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (CFU/ carrier)
		Lot No. P09299002	**Lot No. P10231001**	
484070-01	Carbapenem-Resistant *Escherichia coli*) with organic soil load	0/10	1/10	1.13×10^5
	Carbapenem-Resistant *Escherichia coli*) without organic soil load	---	0/10	1.74×10^5
484070-01	Carbapenem-Resistant *Klebsiella pneumoniae* with organic soil load	0/10	1/10	4.45×10^5
	Carbapenem-Resistant *Klebsiella pneumoniae* without organic soil load	---	0/10	5.32×10^5
		Lot No. P09300001	**Lot No. P10145001**	
484070-02	*Klebsiella pneumoniae* bla_{NDM-1}	0/10	0/10	3.66×10^5
		Lot No. P09209001		
484070-07	*Trichophyton mentagrophytes* 5-minute contact time	1°=0/10 2°=0/10	---	1.17×10^5
	Trichophyton mentagrophytes 6-minute contact time	1°=0/10 2°=0/10	---	

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1 mL)
			Lot No. P09209001	**Lot No. P10231001**	
484070-03	Duck hepatitis B virus 1-minute contact time	10^{-2} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{5.25}$ and $10^{4.75}$ $TCID_{50}$/1.0 mL
		$TCID_{50}$/1.0 mL	$\leq 10^{1.5}$	$\leq 10^{1.5}$	
484070-04	Duck hepatitis B virus 1-minute contact time	10^{-2} to 10^{-4} dilutions	Complete inactivation	---	$10^{6.0}$ $TCID_{50}$/1.0 mL
		$TCID_{50}$/1.0 mL	$\leq 10^{1.5}$	---	
484070-05	Bovine viral diarrhea virus 1-minute contact time	10^{-1} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{5.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
484070-06	Bovine viral diarrhea virus 1-minute contact time	10^{-1} to 10^{-4} dilutions	Complete inactivation	---	$10^{5.0}$ and $10^{5.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-08	Rotavirus 30-second contact time	10^{-1} to 10^{-7} dilutions	Complete inactivation	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
	Rotavirus 1-minute contact time	10^{-1} to 10^{-7} dilutions	Complete inactivation	---	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1 mL)
			Lot No. P09209001	Lot No. P10231001	
484070-09	Human coronavirus 30-second contact time	10^{-1} to 10^{-6} dilutions	Complete inactivation	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
	Human coronavirus 1-minute contact time	10^{-1} to 10^{-6} dilutions	Complete inactivation	---	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-10	Influenza A (H1N1) virus 30-sec contact time	10^{-1} to 10^{-8} dilutions	Complete inactivation	---	$10^{6.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-11	Swine influenza A (H1N1) virus 30-sec contact time	10^{-1} to 10^{-8} dilutions	Complete inactivation	---	$10^{6.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-12	Respiratory syncytial virus 30-sec contact time	10^{-1} to 10^{-6} dilutions	Complete inactivation	---	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
	Respiratory syncytial virus 1-minute contact time	10^{-1} to 10^{-6} dilutions	Complete inactivation	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-13	Adenovirus type 2 30-second contact time	10^{-1} to 10^{-8} dilutions	Complete inactivation	---	$10^{6.0}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
	Adenovirus type 2 1-minute contact time	10^{-1} to 10^{-8} dilutions	Complete inactivation	---	$10^{7.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-14	Avian influenza A (H3N2) virus 30-sec contact time	10^{-1} to 10^{-7} dilutions	Complete inactivation	---	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
	Avian influenza A (H3N2) virus 1-minute contact time	10^{-1} to 10^{-7} dilutions	Complete inactivation	---	$10^{5.25}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-15	Influenza A virus 30-second contact time	10^{-1} to 10^{-7} dilutions	Complete inactivation	---	$10^{6.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
	Influenza A virus 1-minute contact time	10^{-1} to 10^{-7} dilutions	Complete inactivation	---	$\geq 10^{7.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-16	Murine norovirus 1-minute contact time	10^{-1} to 10^{-8} dilutions	Complete inactivation	---	$10^{6.5}$ $TCID_{50}$/0.1 mL
		PFU_{50}/0.25 mL	$\leq 10^{0.5}$	---	
	Murine norovirus 3-minute contact time	10^{-1} to 10^{-8} dilutions	Complete inactivation	---	$10^{5.75}$ $TCID_{50}$/0.1 mL
		PFU_{50}/0.25mL	$\leq 10^{0.5}$	---	
	Feline calicivirus 1-minute contact time	10^{-1} to 10^{-4} dilutions	Complete inactivation	---	$10^{6.5}$ and $10^{5.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1 mL)
			Lot No. P09209001	Lot No. P10231001	
484070-17	Feline calicivirus 3-minute contact time	10^{-1} to 10^{-4} dilutions	Complete inactivation	---	$10^{5.75}$ and $10^{5.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-18	Rhinovirus type 37 1-minute contact time	10^{-1} to 10^{-6} dilutions	Complete inactivation	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
	Rhinovirus type 37 3-minute contact time	10^{-1} to 10^{-6} dilutions	Complete inactivation	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
	Rhinovirus type 37 5-minute contact time	10^{-1} to 10^{-6} dilutions	Complete inactivation	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	---	
484070-19	Poliovirus type 2 1-minute contact time	10^{-1} dilution	Cytotoxicity	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		10^{-2} to 10^{-7} dilutions	Complete inactivation	---	
		$TCID_{50}$/0.1 mL	$\leq 10^{1.5}$	---	
		Log reduction	≥ 3.0 $\log_{10}$	---	
	Poliovirus type 2 3-minute contact time	10^{-1} dilution	Cytotoxicity	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		10^{-2} to 10^{-7} dilutions	Complete inactivation	---	
		$TCID_{50}$/0.1 mL	$\leq 10^{1.5}$	---	
		Log reduction	≥ 3.0 $\log_{10}$	---	
	Poliovirus type 2 5-minute contact time	10^{-1} dilution	Cytotoxicity	---	$10^{4.5}$ $TCID_{50}$/0.1 mL
		10^{-2} to 10^{-7} dilutions	Complete inactivation	---	
		$TCID_{50}$/0.1 mL	$\leq 10^{1.5}$	---	
		Log reduction	≥ 3.0 $\log_{10}$	---	

VI. CONCLUSIONS

1. The submitted efficacy data **support** the use of the product, SDC3A, as a disinfectant with bactericidal activity against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 2-minute contact time:

Carbapenem Resistant *Escherichia coli*	MRID 484070-01
Carbapenem Resistant *Klebsiella pneumoniae*	MRID 484070-01
Klebsiella pneumoniae bla_{NDM-1}	MRID 484070-02

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. [Note that repeat testing was conducted on one product lot against Carbapenem Resistant *Escherichia coli* and Carbapenem Resistant *Klebsiella pneumoniae* after testing in the presence of organic soil showed unacceptable positives.] Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID 484070-07) **support** the use of the product, Axen30 (identical in composition to the product, SDC3A), as a disinfectant with fungicidal activity against *Trichophyton mentagrophytes* on pre-cleaned, hard, non-porous surfaces for both a 5-minute and 6-minute contact time. Complete killing was observed in the subcultures of the required number of carriers tested against one product lot. Neutralization confirmation testing showed positive growth of the microorganism. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

3. The submitted efficacy data **support** the use of the product, SDC.0003.AA0 (an internal identifier for the product, SDC3A), as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 1% organic soil load (a 100% organic soil load for Duck hepatitis B virus) for a 1-minute contact time:

Duck hepatitis B virus	MRID 484070-03 and -04
Bovine viral diarrhea virus	MRID 484070-05 and -06

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested. In studies against Duck Hepatitis B and Bovine viral diarrhea virus, the initial and confirmatory studies were performed at the same laboratory but under the direction of different study directors. Both the initial and confirmatory studies tested two replicates per product lot. The confirmatory study tested one product lot, not the standard two product lots.

4. The submitted efficacy data **support** the use of the product, Axen30 (identical in composition to the product, SDC3A), as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 1% organic soil load for the contact times listed:

Rotavirus	30 seconds, 1 minute	MRID 484070-08
Human coronavirus	30 seconds, 1 minute	MRID 484070-09
Influenza A (H1N1) virus	30 seconds	MRID 484070-10
Swine influenza A (H1N1) virus	30 seconds	MRID 484070-11
Respiratory syncytial virus	30 seconds, 1 minute	MRID 484070-12
Adenovirus type 2	30 seconds, 1 minute	MRID 484070-13
Avian influenza A (H3N2) virus	30 seconds, 1 minute	MRID 484070-14
Influenza A virus	30 seconds, 1 minute	MRID 484070-15
Murine norovirus	1 and 3 minutes	MRID 484070-16
Feline calicivirus	1 and 3 minutes	MRID 484070-17
Rhinovirus type 37	1, 3, and 5 minutes	MRID 484070-18
Poliovirus type 2	1, 3, and 5 minutes	MRID 484070-19

Recoverable virus titers of at least 10^4 were achieved. In studies against Poliovirus type 2, cytotoxicity was observed in the 10^{-1} dilution. Complete inactivation (no growth) was indicated in all higher dilutions tested. At least a 3-log reduction in titer was demonstrated beyond the cytotoxic level. In studies against all other viruses, cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested. One product lot was tested.

VII. LABEL

1. The proposed label claims that the product, SDC3A, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 2-minute contact time:

Carbapenem Resistant *Escherichia coli*
Carbapenem Resistant *Klebsiella pneumoniae*
Carbapenem Resistant *Klebsiella pneumoniae*, NDM-1 +

These claims are acceptable as they are supported by the submitted data.

2. The proposed label claims that the product, SDC3A, is an effective disinfectant against *Trichophyton mentagrophytes* on pre-cleaned, hard, non-porous surfaces for a 5-minute contact time. This claim is acceptable as it is supported by the submitted data.

3. The proposed label claims that the product, SDC3A, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 1-minute contact time:

Hepatitis B virus (as Duck hepatitis B virus)
Hepatitis C virus (as Bovine diarrhea virus)
Murine norovirus
Norovirus (as Feline calicivirus)
Poliovirus type 2
Rhinovirus type 37

These claims are acceptable as they are supported by the submitted data.

4. The proposed label claims that the product, SDC3A, is an effective disinfectant against the following microorganisms on pre-cleaned, hard, non-porous surfaces for a 30-second contact time:

Adenovirus type 2
Avian influenza A virus
Human coronavirus
Influenza A virus
Influenza A (H1N1) virus
Respiratory syncytial virus
Rotavirus
Swine influenza A (H1N1) virus

These claims are acceptable as they are supported by the submitted data.

5. The following revision to the proposed label must be made:

- On page 2 of the proposed label, change "Fiberglass" to read "**Sealed** fiberglass." Fiberglass is a porous surface.

6. As stated in past reviews, contact time and kill time are synonymous. To present kill time that is different than the contact time is misleading to the end-user.